

### **REMARKS**

Reconsideration of this application is respectfully requested. Claims 1-27 and 29-43 are pending and at issue.

#### ***Indefiniteness Rejection***

Claims 1-27 and 29-43 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite. According to the Examiner, “[i]t is unclear if the diol in solution and the diol in precipitate are in protonated or unprotonated form in the various steps, because the claims use these terms interchangeably.” Office Action, page 2. The Examiner also suggests that the diols should be referred to by their chemical names because it is improper to incorporate matter into the claims by reference to the specification.

Applicants respectfully traverse this rejection, and request reconsideration.

The standard for definiteness is whether one of ordinary skill in the art would understand what is claimed when the claims are read in light of the specification. *See* MPEP § 2173. Each time the claims recite an RS-, R- or S-diol, whether as a precipitate or in solution, they specify that the diol is either the “free base or acid addition salt thereof.” Thus, a skilled artisan would understand that each recited diol in the claims is independently either a free base or acid addition salt thereof.

The terms “R-diol,” “S-diol,” and “RS-diol” are defined at page 5, lines 17-27, of the specification by their full chemical names. It is well-settled that the applicant is permitted to be his own lexicographer and define claim terms according to a specialized meaning. *See* MPEP § 2173.05(a) (“When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning.”). Therefore, these terms are definite.

Accordingly, the claims are definite, and applicants respectfully request that the rejection be withdrawn.

### ***Enablement Rejection***

Claims 1-27 and 29-43 have been rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. The Examiner asserts that the nature of the invention, “enriching one enantiomer over the other starting from [a] slightly enriched mixture of enantiomers by means of precipitation,” is not discussed in the specification. Also, according to the Examiner, the information in the examples is insufficient in several ways: the amount of enriched isomer or racemate is not provided, no description is made of the unextracted material remaining in the final solution phase, the form of the diol precipitate is not specified, and no information is provided about using HPLC to characterize the residue/precipitate obtained in the process.

Applicants respectfully traverse this rejection, and request reconsideration.

None of what the Examiner cites as lacking in the specification is required to satisfy the enablement requirement. The specification must enable one skilled in the art to make and use what is claimed without undue experimentation. MPEP § 2164.01. It is not necessary to provide a dissertation on the nature and theory of the invention. Moreover, details about yields, unextracted material, and characterization of the isolated product are not elements of the claims.

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *United States v. Teletronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988) (emphasis added); *see also* MPEP § 2164.01 (“A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991).”).

The claims recite the necessary steps to obtain the claimed racemic diol and/or R- or S-diol from an initial non-racemic mixture of R- and S-diol. The specification describes these steps, including in detail in the working examples. *See* Specification, pages 7-28. Further details of the methods to perform these steps, including techniques to calculate product yields and characterize

the unextracted material and enriched product (such as by HPLC) are well-known to the skilled artisan and routinely performed. *See, e.g.,* Vogel's Textbook of Practical Organic Chemistry, 3<sup>rd</sup> ed. (1956), pp. 201-204 (Exhibit A); Godwin W. Fong et al., HPLC in the Pharmaceutical Industry (1991), pp. iii-iv (Exhibit B). Therefore, undue experimentation would not be required to practice the claimed invention because the teaching of the specification, in combination with the knowledge of the skilled artisan, is sufficient to perform each of the claimed steps. *See* MPEP § 2164.01 ("The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983).").

Applicants also note that, contrary to the Examiner's contention, the form of the diol precipitate is specified by the working examples. The title of each example states whether the precipitated diol is a free base or an acid addition salt. The precipitates in Examples 1 and 4-9 are obtained as acid addition salts. In Examples 2 and 3, the free base is obtained.

Moreover, the Examiner has the initial burden of providing evidence to show why enablement should be questioned. *See* MPEP § 2164.04. There are several factors that the Examiner must consider in weighing all the evidence. *See* MPEP § 2164.01(a). Here, the Examiner has not made any findings regarding many of these factors, such as the state of the prior art, the level of one of ordinary skill, and the level of predictability in the art. As discussed above, the techniques required to practice the invention are routinely carried out by the skilled artisan. These techniques often yield high predictability. Therefore, The Examiner has not met his burden of providing sufficient evidence to question why the skilled artisan would not be able to make and use the claimed invention.

For at least the above reasons, the rejection of the claims for lack of enablement is improper. Applicants respectfully request that the rejection be withdrawn.

In view of the above remarks, Applicants believe the pending application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved

through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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